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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 3 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Reregistration of Dicamba. Corn Processing Study. CBRS Nos. 8592/8593 and 9190; DP BARCODEs D168900 and D173018; MRID 40547909.

FROM: Paula A. Deschamp, Biologist
Reregistration Section I
Chemistry Branch II: Reregistration Support
Health Effects Division (H7509C)

THRU: E. Zager, Chief
Chemistry Branch II: Reregistration Support
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TO: Lois Rossi/Judith Coombs
Reregistration Branch
Special Review and Reregistration Division (H7508C)

Attached is the review of residue chemistry data submitted by Sandoz Crop Protection Corp. in response to reregistration requirements for a corn processing study. This information was reviewed by Acurex Corporation under supervision of CBRS, HED. The data assessment has undergone secondary review in the Branch and has been revised to reflect Branch policies.

It is recommended that a copy of this review be sent to the Registrant.

If you need additional input, please advise.

Attachment 1: Dicamba (CBRS Nos. 8592/8593 and 9190 [DP Barcodes D168900 and D173018]. Registrant's Response to Residue Chemistry Data Requirements.

cc: PADeschamp (CBRS), Circulate, Dicamba Reg. Std. File, SF, RF, C. Furlow (PIB/FOD).

H7509C:CBRS:PAD:pad:CM#2:Rm812B:703-305-6227:04/03/92
RDI: MMetzger:04/03/92 EZager:04/03/92

DICAMBA
(Chemical Code 029801)
(CBRS Nos. 8592 and 8593; DP Barcode D168900)
(CBRS No. 9190; DP Barcode D173018)

TASK 3

Registrant's Response to Residue Chemistry Data Requirements

March 27, 1992

Contract No. 68-DO-0142

Submitted to:

U.S. Environmental Protection Agency
Arlington, VA 22202

Submitted by:

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DICAMBA

(Chemical Code 029801)

(CBRS Nos. 8592 and 8593; DP Barcode D168900)
(CBRS No. 9190; DP Barcode D173018)

REGISTRANT'S RESPONSE TO RESIDUE CHEMISTRY DATA REQUIREMENTS

Task-3

BACKGROUND

The Dicamba Guidance Document dated 6/89 required data from a corn processing study. In response, Sandoz Crop Protection Corp. submitted data on corn grain processed commodities from wet and dry milling (1989; MRID 41187301). These data are reviewed here for their adequacy in fulfilling Guidance Document requirements. The Conclusions and Recommendations stated below apply only to the magnitude of the residue in corn processed commodities.

SRRD also requested review of MRIDs 00144369, 00146366, 00148127, 00159577, and 40547909 under the cited DP Barcodes. These documents contain data that pertain to other chemicals or are otherwise not applicable to the residue chemistry data requirements for dicamba. Refer to the Bibliography for details.

The qualitative nature of the residue in plants is adequately understood. The residues of concern in or on plant commodities are dicamba and its metabolite 3,6-dichloro-5-hydroxy-o-anisic acid (40 CFR §180.227[a], §185.1800, and §186.1800), except in or on asparagus, soybeans, and soybean forage and hay. The residues of concern in soybeans and soybean forage and hay (40 CFR §180.227[b]) and asparagus are dicamba and its metabolite 3,6-dichloro-2-hydroxybenzoic acid. The Dicamba SRR Residue Chemistry Chapter (6/30/89) states that asparagus should be listed under 40 CFR §180.227[b] instead of [a], because the predominant terminal residue in asparagus is 3,6-dichloro-2-hydroxybenzoic acid. Method I in PAM, Vol. II is adequate for enforcement of tolerances for dicamba and its metabolite 3,6-dichloro-5-hydroxy-o-anisic acid (5-hydroxy dicamba). The Guidance Document required independent laboratory validation of methods AM-0691A and AM-0691B for dicamba and its metabolites 5-hydroxy dicamba and 3,6-dichloro-2-hydroxybenzoic acid, prior to consideration of the method for enforcement.

No Codex MRLs have been established for residues of dicamba. Therefore, there are no questions of compatibility with respect to the U.S. tolerances and Codex.

CONCLUSIONS/RECOMMENDATIONS

These data fulfill the requirement for a corn processing study. Residues of dicamba and its 5-hydroxy metabolite did not concentrate in starch, crude oil, or refined oil from wet milling; nor in grits, meal, flour, crude oil, or refined oil from dry milling; thus food/feed additive tolerances for corn processed products are not needed. No additional data are required for this topic.

DETAILED CONSIDERATIONS

Residue Analytical Methods

Sandoz Crop Protection Corp. (1989; MRID 41187301) submitted data from a corn grain processing study generated using method AM-0691B. The method quantifies dicamba and its 5-hydroxy metabolite. In this method, residues are hydrolyzed with 1 N hydrochloric acid at 95 °C for 1.5 hours, adjusted to pH >8, then to pH 1 and extracted with ethyl ether. For soapstock, the sample is dissolved in 5 mL of 1 N potassium hydroxide and 30 mL of 1 N hydrochloric acid is added prior to hydrolysis. The residues are methylated with diazomethane and cleaned up on silica gel eluted with ethyl ether in pentane. Residues are analyzed using GLC/ECD. The registrant reported a detection limit of 0.01 ppm for each compound, but did not validate the method at this level. Included in the method description were validation data on several crops. Recovery of dicamba was 96 and 98% from corn grain fortified at 0.05 and 0.5 ppm, respectively, and recovery of the 5-hydroxy metabolite was 96 and 90%.

Recoveries determined concurrently with test samples from the processing study are reported in Table 1. Note that the 0.01 ppm limit of detection reported by the registrant was not validated by the recovery data. Grain and processed commodity samples were fortified with each compound at 0.1 ppm. The recoveries were acceptable for grain, flour, meal, grits, and gluten. Recovery was also acceptable for soapstock after modification of the extraction procedures. The initial recoveries of dicamba and its 5-OH metabolite from starch and oil (crude and refined) were typically low. Upon reanalysis, recoveries from these samples generally improved; however, no explanation was provided for the variability between initial and reanalysis recovery values.

Table 1. Residues of dicamba and 5-hydroxy (OH) dicamba in or on corn grain and processed fractions presented with concurrent recoveries from control samples fortified with each compound at 0.1 ppm.

	Residues (ppm)		Recovery (%)	
	dicamba	5-OH dicamba	dicamba	5-OH dicamba
Dry milling				
grain	0.281	0.010	87	106
hulls	0.109	<0.01	53, 103[a]	113
flour	0.089	<0.01	89	111
meal	0.024	<0.01	81	116
soapstock	<0.01	<0.01	36, 64[b]	0, 71[b]
crude oil (expelled)	<0.01	<0.01	48, 58[a]	64, 97[a]
refined oil	<0.01	<0.01	41, 72[a]	41, 48[a]
large grits	0.070	<0.01	78	116
crude oil (extracted)	<0.01	<0.01	64, 87[a]	71, 55[a]
Wet milling				
grain	0.415	<0.01	86	71
gluten	0.050	<0.01	81	95
hulls	0.014	<0.01	95	89
soapstock	0.027	<0.01	14, 85[b]	20, 79[b]
starch	<0.01	<0.01	50, 87[a]	47, 102[a]
crude oil (expelled)	<0.01	<0.01	70	98
crude oil (extracted)	<0.01	<0.01	82, 78[a]	58, 52[a]
refined oil	<0.01	<0.01	75	93

[a]The second value represents reanalysis of the same sample; no explanation for differences in recovery was provided. [b]Reanalysis of soapstock samples was conducted following a modified extraction procedure.

Magnitude of the Residue in Plants

Corn grain: A tolerance of 0.5 ppm has been established for combined residues of dicamba and its metabolite 3,6-dichloro-5-hydroxy-o-anisic acid in or on corn grain (40 CFR §180.227[a]).

Sandoz Crop Protection Corp. (1989; MRID 41187301) submitted data from a corn grain processing study. The 4 lb/gal SC/L potassium salt formulation was applied foliarly at 2 and 10 lb ai/A. The registrant stated that this rate was 1 and 5x their labeled rates. Corn grain

was harvested 7 days after application. Grain was frozen within 4 hours of collection and stored for approximately 6 months before processing. Wet and dry milling of the grain were conducted using simulated commercial procedures at the Texas A&M Food Protein Research and Development Center. Grain and processed fractions were stored for 2 months prior to analysis. Storage temperatures were around -18 °C.

Analyses were conducted using method AM-0691B, described above. The results are presented in Table 1. Residues of dicamba and its 5-hydroxy metabolite did not concentrate in starch, crude oil, or refined oil from wet milling; nor in grits, meal, flour, crude oil, or refined oil from dry milling of corn grain.

References (used):

41187301 Bade, T. (1989) Dicamba Residues in Corn Processing Fractions from a Pre-Harvest Application of Banvel: Laboratory Project ID: 480068: Report No. 104. Unpublished study prepared by Sandoz Crop Protection Corporation. 182 p.

References (not used):

[The following MRIDs contain data pertaining to chemicals other than dicamba.]

00146366 Goins, P. (1984) Sanitizing Activity of Sanitizing Solutions. Unpublished study prepared by Missouri Analytical Laboratories, Inc. 3 p.

00159577 Allen, J.; Proudlock, R.; Pugh, L. (1986) Technical Cycloheximide: Mouse Micronucleus Test: Study No. TOX 85113: Schedule No. FSB 231/8661. Unpublished study prepared by Huntingdon Research Centre. 27 p.

00144369 Prince, H. (1984) Virucide Assay of Staphene Disinfectant. Unpublished compilation prepared by Gibraltar Biological Laboratories. 12 p.

[The following MRID was cited in the 6/89 Guidance Document under Magnitude of the Residue in Animals.]

00148127 Cahill, W.; Johnson, L. (1984) Determination of Dicamba Residue in Laying Hen Tissues and Eggs after a 28 Day Feeding Study: Project No. 480068. Unpublished study prepared by Velsicol Chemical Corp. 98 p.

[The following MRID contains data generated by Craven Laboratories.]

40547909 Suzuki, H. (1983) Postemergence Banvel Formulations: Sorghum Residue Study: Laboratory project ID 480068-60. Unpublished study prepared by Velsicol Chemical Corporation. 31 p.